EXHIBIT 12

浙江华海药业股份有限公司
ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.

偏差调查报告
Deviation Investigation Report

产品名称 Product name：	缬沙坦 API /Valsartan API
偏差主题 Deviation title：	关于缬沙坦 API（三乙胺工艺）中未知杂质（基因毒性杂质）的调查 Investigation regarding unknown impurity (genotoxic impurity) of Valsartan API (TEA process)
偏差编号 No.：	DC_E-18003(Version 2)
发生日期 Date of incident：	2018.07.08
编写日期 Prep. date：	2018.11.05
报告编写 Prepared by：	赵彩凤 Zhao Caifeng

浙江华海药业股份有限公司
ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.

- Sodium azide might introduce NO_2^-
- Potable water might introduce NO_2^-

基于以上风险分析和评估，对各原料中存在风险点的饮用水、饱和食盐水 DMF、叠氮钠、、三乙胺盐酸盐中的残留进行检测，相关检测结果及评估见下表：

Based on the risk analysis and evaluation, the raw mateirals with risk point identified, i.e., potanble water, saturated NaCl solution, DMF, soudium azide, Triethylamine HCl were analyzed accordingly. The resylts are summarized as follows:

表 4-25：原料检测结果汇总表

Table 4-25 Raw material test results

原料名称 \Name	可能引入杂质 Impurites might introduced	批号. Batch No	DMA (ppm)	DEA (ppm)	NDEA (ppm)	NDMA (ppm)	NO_2^- (ppm)	Result
饮用水 Potable water	NDMA NDEA NO_2^-	20181015	NA	NA	＜LOD（LOD：0.01ppm）	＜LOD（LOD：0.01ppm）	＜LOD（LOD：0.01ppm）	各项指标仅考虑最低检测值且绝对量富集情况下对 NDMA/NDEA 形成具有一定风险 Might present certain extent of risk to form NDMA/.NDEA
DMF	DMA、DEA	SC-3362-1329-100-04	＜LOD（LOD：10ppm）	＜LOD（LOD：4.5ppm）	NA	NA	NA	DMF 中 DMA、DEA 对亚硝基化合物的影响可忽略。The risk of DMA and DEA in DMF to nitrosoamines is negligible
叠氮钠 Sodium azide	NO_2^-	SC-3362-1329-099-07	NA	NA	NA	NA	＜LOD（LOD：0.6pm）	叠氮钠中的亚硝酸根对 NDMA/NDEA 形成具有一定风险。The NO2- in sodoium azide might present certain extent of risk to form NDMA/NDEA

的形成机理，应是三乙胺盐酸盐中有二乙胺杂质，与亚硝酸发生亚硝化反应生成 NDEA 杂质，从而带入粗品中，最后残留到缬沙坦成品。

In toluene solution of Pentanoyl Compound, DMA, DEA, NDMA and NDEA were not detected. NDEA was detected in the reaction system after quenching in valsartan crude product process. In the crude product process, toluene was used as solvent and triethylamine hydrochloride as catalyst in the reaction of tetrazole. After the reaction, the material was quenched with sodium nitrite without separation. According to the previous raw material investigation, i.e. presence of diethylamine impurities in triethylamine hydrochloride, combined with the formation mechanism of NDEA, it should be the nitrosation of diethylamine impurities (in triethylamine hydrochloride) by nitrite to produce NDEA impurities, which is carried over into crude products, and finally remain in valsartan finished products.

- NDMA 生成风险分析 The risk analysis of NDMA generation

因为三乙胺盐酸盐原料中部分批次中可能存在少量的二甲胺杂质（供应商设备共线交叉污染，以及乙醇中存在的甲醇杂质），由于淬灭过程有机相未与水层分离，淬灭是在有产品的条件下进行的，淬灭时体系中二甲胺会与亚硝酸发生亚硝化反应生成 NDMA 会带入粗品，并最终带入成品。

Because there may be a small amount of dimethylamine impurities in some batches of triethylamine hydrochloride raw materials (cross-contamination of suppliers' equipment, and methanol impurities in ethanol). And the organic phase is not separated from the water layer during quenching process, quenching is carried out under the conditions of products. Dimethylamine and nitrite in the system would be nitrosated during quenching to produce NDMA, which will be carried into crude products and eventually into the finished products.

4.5.6.3 缬沙坦(氯化锌工艺、三乙胺淬灭工艺)NDMA、NDEA 产生结论 Conclusion of NDMA and NDEA Formation in Valsartan (ZnCl2 Process and TEA Process)

- 缬沙坦产品中 NDMA 产生 NDMA formation in Valsartan